

appears that all of Respondent's customers are convenience stores and gas stations, which are non-traditional retailers of list I chemical products and entities which DEA has repeatedly found are conduits for the diversion of these products into the illicit manufacture of methamphetamine.

Here, unlike in other cases where the Government's evidence established that a distributor had made excessive sales and that these sales supported a finding of diversion, the Government's proof does not support such a finding. Nonetheless, Respondent's wholly inadequate recordkeeping substantially hinders the efforts of this Agency and its local partners to investigate the suppliers of methamphetamine traffickers and the traffickers themselves. Moreover, even if Respondent's recordkeeping is attributable to neglect, it still impedes the protection of public safety. I therefore conclude that this factor also supports a finding that Respondent's continued registration would be inconsistent with the public interest.

In sum, Respondent violated Federal law by distributing products from an unregistered location. Indeed, this misconduct is especially egregious because he did so even after being told by a DEA official to stop. Respondent also does not maintain effective controls against diversion as evidenced by his wholly inadequate recordkeeping and the inadequate security he provided for list I products. Moreover, notwithstanding his years of experience distributing list I chemicals, Respondent clearly lacked knowledge of which products contained listed chemicals and he did not even know what the Code of Federal Regulations is. Finally, Respondent's attitude reflects indifference to his obligations under federal law and regulations. Given all of the above, it is indisputable that Respondent's continued registration would be inconsistent with the public interest.

Order

Accordingly, pursuant to the authority vested in me by 21 U.S.C. 823(h) & 824(a), as well as 28 CFR 0.100(b) & 0.104, I order that DEA Certificate of Registration, 002964JTY, issued to John J. Fotinopoulos be, and it hereby is, revoked. I further order that the pending applications for modification and renewal of the registration issued to John J. Fotinopoulos be, and they hereby are,

the possession of individuals apparently involved in the illicit manufacture of methamphetamine").

denied. This order is effective June 4, 2007.

Dated: April 25, 2007.

Michele M. Leonhart,

Deputy Administrator.

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DEPARTMENT OF JUSTICE

Drug Enforcement Administration

[Docket No. 06-52]

Green Acres Farms, Inc.; Denial of Application

On February 6, 2006, the Deputy Assistant Administrator, Office of Diversion Control, Drug Enforcement Administration, issued an Order to Show Cause to Green Acres Farms, Inc., (Respondent) of Tacoma, Washington. The Show Cause Order proposed to deny Respondent's pending application for registration as a bulk manufacturer of the Schedule I controlled substances marijuana and tetrahydrocannabinols, on the grounds that its registration would be inconsistent with the public interest, *see* 21 U.S.C. 823(a), and with the United States' obligations under the Single Convention on Narcotic Drugs, March 30, 1961, 18 U.S.T. 1407. Show Cause Order at 1.

More specifically, the Show Cause Order alleged that on June 28, 2004, Respondent's owners, Mr. and Mrs. Keith Yale, submitted an application to DEA to manufacture marijuana and tetrahydrocannabinols and that DEA then sent the Yales a standardized questionnaire which all applicants for registration to manufacture controlled substances in Schedules I and II are required to complete. *See id.* The Show Cause Order alleged that Respondent's owners indicated on the questionnaire that the firm sought to grow marijuana to supply "persons who qualify to receive marijuana under the Washington State Medical Use of Marijuana Act." *See id.* at 2. The Show Cause Order further alleged that Mrs. Yale stated on the questionnaire that she had obtained authorization from a physician to use marijuana and that she planned to use some of the marijuana grown by Respondent. *Id.* The Show Cause Order also alleged that Respondent intended "to supply marijuana to patients in other states, which have laws that permit the 'medical use' of marijuana," and that Respondent also intended to distribute its marijuana to Washington-based pharmacies and cooperatives. *Id.* The Show Cause Order alleged that Respondent's owners had also stated

that they intended to extract THC from their marijuana and develop an ingestible form of medication to create an alternative to smoked marijuana. *Id.*

The Show Cause Order further alleged that neither marijuana nor tetrahydrocannabinols have been approved under the Food, Drug and Cosmetic Act, as "safe and effective" for medical use, and neither drug has an "accepted medical use in * * * the United States." *Id.* at 3 (citing 21 U.S.C. 321(p) & 812(b)(1)(B)). Relatedly, the Show Cause Order alleged that Respondent's proposed distribution of marijuana would constitute a felony under 21 U.S.C. 841(a)(1). *Id.* at 4. Finally, the Show Cause Order alleged that Respondent's proposed activity was not permitted under the Washington act. *See id.* at 4.

Respondent requested a hearing; the matter was assigned to Administrative Law Judge (ALJ) Mary Ellen Bittner. Thereafter, the Government moved for summary disposition.¹

The basis for the Government's motion was that marijuana and tetrahydrocannabinols have not been approved under the Food, Drug and Cosmetic Act, 21 U.S.C. 321(p), as "safe and effective" for medical use. Gov. Mot. at 3-4. The Government also argued that both marijuana and tetrahydrocannabinols are Schedule I controlled substances and "have no currently accepted medical use in treatment in the United States." *Id.* (citing 21 U.S.C. 812(b)(1)(B)). Relatedly, the Government argued that "there is a lack of accepted safety for use of these [drugs] under medical supervision." *Id.* (citing 21 U.S.C. 812(b)(1)(C)). The Government further noted this Agency's previous denial of a similar application to grow marijuana for medical use. *Id.* at 5 (citing *Church of the Living Tree*, 68 FR 17403 (2003)).

The Government also argued that in *United States v. Oakland Cannabis Buyer's Coop*, 532 U.S. 483 (2001), the Supreme Court had rejected the "medical necessity" defense raised by an entity which distributed marijuana for purportedly medical purposes. Gov. Mot. at 5. According to the Government, "any distribution of marijuana as proposed by [Respondent] would constitute an unlawful distribution of a controlled substance in violation of 21 U.S.C. 841(a)(1), a felony." The Government further contended that unless and until "these substances are

¹ Upon being directed by the ALJ to file a response to the Government's motion, Respondent sought a six month extension. The ALJ concluded, however, that an extension of such duration would unduly delay the proceedings. Instead, the ALJ granted Respondent a sixty day extension.

approved [by the FDA] for medical use and placed in a Schedule other than Schedule I, DEA cannot grant an application to manufacture * * * these substances to anyone who seeks to manufacture [them] for the purpose of distributing * * * or dispensing [them] to [] 'patients.' " *Id.*

The Government also argued that marijuana and tetrahydrocannabinols are Schedule I controlled substances under Washington law and that the State's Medical Use of Marijuana Act creates only "a narrow exception to the classification of marijuana as a Schedule I controlled substance." *Id.* at 5–6. According to the Government, the exception allows only a "qualifying patient" to possess marijuana, and such person may only "possess no more marijuana than is necessary for the patient's personal, medical use, not exceeding the amount necessary for a sixty-day supply." *Id.* at 6 (quoting RCW section 69.51A.040(2)(b)). The Government thus contends that Respondent's proposed activities go "well beyond what is permitted to be manufactured under applicable Washington * * * law," and thus Respondent would be non-compliant with state law. *Id.* (citing 21 U.S.C. 823(a)(2)) (requiring Attorney General to consider "compliance with applicable State law" in considering application to manufacture Schedule I controlled substances).

In its submission, Respondent's owners stated that "there are no witnesses," that "[a]ll documents have been submitted," and that "[o]ther testimony ha[d] been submitted in the" questionnaire they had previously sent to DEA. Resp. Letter 1 (July 11, 2006). Respondent's owners further stated that it was their "intention to manufacture, package and sell [marijuana] to the various authorized outlets (state pharmacies within the state of Washington)." *Id.* With respect to the legal issue presented, Respondent stated that it is "[t]he position and law of the State of Washington * * * that certain qualified persons in this State have the right as given by the voice of the people to possess and use marijuana for specific medical needs as described in Washington State law." *Id.* Respondent further maintained that "DEA should allow the State of Washington and [itself] to engage [in] the legal and correct distribution of marijuana." *Id.*

Concluding that there were no material facts in dispute, the ALJ granted the Government's motion. As the ALJ explained, marijuana and tetrahydrocannabinols "have a high potential for abuse, have no currently accepted medical use in treatment, and

lack safety for use in treatment under medical supervision." ALJ Dec. at 3. Because "these substances cannot be manufactured for distribution to patients for medical use," the ALJ concluded that DEA "cannot register an applicant with the intention to manufacture and distribute contrary to federal law." *Id.* Finally, the ALJ also held that the Washington state law exception does not "extend to the manufacturing of these substances and therefore Respondent lacks state authority" to conduct its proposed activity. The ALJ thus recommended that I deny Respondent's application and forwarded the record to me for final agency action. Neither party filed exceptions.

Having considered the record as a whole, I adopt the ALJ's opinion in its entirety and deny Respondent's application. Section 303(a) of the Controlled Substances Act provides that the "Attorney General shall register an applicant to manufacture controlled substances in schedule I or II if he determines that such registration is consistent with the public interest." 21 U.S.C. 823(a). While Congress provided six factors to be considered in determining the public interest, *id.*, it is well settled that I may rely on any one or a combination of factors, and may give each factor the weight I deem appropriate in determining whether an application for registration should be denied. *See ALRA Laboratories, Inc.*, 59 FR 50620, 50621 (1994). Moreover, I am "not required to make findings as to all of the factors." *Hoxie v. DEA*, 419 F.3d 477, 482 (6th Cir. 2005); *Morall v. DEA*, 412 F.3d 165, 173–74 (D.C. Cir. 2005).

Here, it is clear that Respondent's proposed activity would not comply with applicable Federal and State laws and would be inconsistent with public health and safety. *See* 21 U.S.C. 823(a)(2) & (6). Congress placed marijuana (and tetrahydrocannabinols) on Schedule I based on its determination that both substances have "no currently accepted medical use" at all." *Oakland Cannabis Buyers*, 532 U.S. at 483, 491 (2001). Until Congress revises that determination, it is a federal criminal offense to manufacture either of these substances for any purpose other than to supply an FDA pre-approved research project. *See Gonzales v. Raich*, 545 U.S. 1, 14 (2005). Moreover, it also appears that Respondent's proposed activities would violate Washington law. *See State v. Tracy*, 147 P.3d 559, 561–62 (Wash. 2006) (upholding conviction for possession and manufacturing of marijuana because "only qualifying patients are entitled to the defense

under the act"). Accordingly, Respondent's registration would be inconsistent with the public interest. *See* 21 U.S.C. 823(a).

Order

Pursuant to the authority vested in me by 21 U.S.C. 823(a), as well as by 28 CFR 0.100(b) & 0.104, I hereby order that the application of Green Acres Farm, Inc., for a DEA Certificate of Registration to manufacture marijuana and tetrahydrocannabinols be, and it hereby is, denied. This order is effective June 4, 2007.

Dated: April 25, 2007.

Michele M. Leonhart,

Deputy Administrator.

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DEPARTMENT OF JUSTICE

Drug Enforcement Administration

[Docket No. DEA–290R]

Controlled Substances: Proposed Revised Aggregate Production Quotas for 2007

AGENCY: Drug Enforcement Administration (DEA), Justice.

ACTION: Notice of proposed revised 2007 aggregate production quotas.

SUMMARY: This notice proposes revised 2007 aggregate production quotas for controlled substances in schedules I and II of the Controlled Substances Act (CSA).

DATES: Written comments must be postmarked, and electronic comments must be sent, on or before May 24, 2007.

ADDRESSES: To ensure proper handling of comments, please reference "Docket No. DEA–290R on all written and electronic correspondence. Written comments being sent via regular mail should be sent to the Deputy Assistant Administrator, Office of Diversion Control, Drug Enforcement Administration, Washington, DC 20537, Attention: DEA Federal Register Representative/ODL. Written comments sent via express mail should be sent to DEA Headquarters, Attention: DEA Federal Register Representative/ODL, 2401 Jefferson-Davis Highway, Alexandria, VA 22301. Comments may be directly sent to DEA electronically by sending an electronic message to dea.diversion.policy@usdoj.gov. Comments may also be sent electronically through <http://www.regulations.gov> using the electronic comment form provided on that site. An electronic copy of this